

REMARKS

Entry of this Amendment is proper under 37 C.F.R. § 1.116, because the Amendment places the application in condition for allowance for the reasons discussed herein. Entry of the Amendment, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.116, are thus respectfully requested.

As correctly indicated in the Office Action Summary, claims 40-44 and 46-60 are pending in the application and are under consideration; claims 40, 41, 43, 44 and 46-60 stand rejected. Claim 42 has been withdrawn.

By way of the instant Amendment, claims 43, 48-50 and 59 have been canceled without prejudice or disclaimer to the subject matter disclosed therein. Claims 40, 42, 44, 48 and 60 have been amended. Claim 60 has further been re-written in independent form. The amendment to claim 40 is supported throughout the specification, for example at least in Example 3. The amendment to claim 42 is supported throughout the specification and at least in the original claims. The amendment to claim 44 is supported throughout the specification, for example at least at page 5, lines 17-20 and page 6, lines 33-35, and claim 59 as previously presented. Amendments to claims 48 and 60 are likewise supported throughout the specification, for example at least in the Examples, at page 5, lines 17-20, page 6, lines 33-35, and page 13, lines 21-36. No prohibited new matter has been introduced by way of the instant amendment. Applicants reserve the right to file a continuation or divisional application directed to any subject matter that has been canceled by way of this amendment.

With respect to the Information Disclosure Statement

It has been alleged that the Information Disclosure Statement filed August 12, 2001 fails to comply with 37 C.F.R. § 1.988(a)(3), because it does not contain a concise explanation of the relevance of FR 2706486. Applicants note that FR 2706486 relates to nucleic acid sequences encoding intracellular binding proteins. More particularly, the nucleic acid comprises a gene coding for a single chain antibody specific for a ras oncogene under the control of a promoter. For a further indication of the relevance of FR 2706486, the Examiner's attention is directed to U.S. Patent No. 6,159,947, which is a U.S. member of the family of FR 2706486 as indicated by the notation on its face of priority to foreign application FR 93 07241, which was published under FR 2706486.

A new Information Disclosure Statement is attached hereto listing these documents. A copy of U.S. Patent No. 6,159,947 is attached. It is understood that FR 2706486 has been placed in the file. The Examiner's consideration of the documents is respectfully requested.

Election/ Restriction Claim Objections

Claims 41, 41, 43-48 and 51-60 have been objected to as encompassing non-elected subject matter. Claims 40, 44 and 60 have been amended to recite the elected species. Claim 42 has been amended to recite that the modification recited therein is in addition to the modification recited in claim 40. Accordingly, claim 42 incorporates all the features of the elected species. Rejoinder of claim 42 with the elected group is respectfully requested. Withdrawal of the objection to claims 41, 41, 43-48 and 51-60 as encompassing non-elected subject matter is respectfully requested.

Title

The title has been amended in accordance with the Examiner's suggestion.

Claim rejections under 35 U.S.C. § 112, first paragraph, enablement:

Claims 48-50 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. Applicants do not accede to the reasons for the rejection. Substantial evidence has been submitted that the biological material required to practice the invention is both well known and available since it has previously been deposited in a depository for patent purposes by the creators of the material. However, simply in order to expedite prosecution of Applicant's other claims and to reduce the number of issues on appeal should an appeal be necessary, claims 48-50 have been canceled. Applicants reserve the right to reintroduce claims directed to the canceled subject matter in this application or a subsequent application.

Claim rejections under 35 USC § 112, written description:

Claims 48 and 60 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter that was not sufficiently described in the specification. The rejection is respectfully traversed. Claim 48 has been canceled. Claim 60 has been amended. It is alleged that the recitation of "fusion to a toxic substance and an immunopotentiating substance" is not supported by a written description. Applicants respectfully submit that claiming an invention as broadly comprising features in the alternative does not preclude the features also appearing in combination where the features are clearly susceptible of being used in combination and where the combination is explicitly disclosed in that the features appear together in a preferred example. See, for example, page 12, lines 21-36. Examples 4 and 6 of the specification exemplify making a vector with the combination of features recited in claim 60. One of skill in the art would surely consider that

that inventors were in possession of the vector of claim 60 which simply describes the features found in a working example.

Moreover, explicit support for the claimed combination is also found in the original claims. The Examiner's attention is directed to original claims 20 and 21. Claim 20 recites that the antibody is modified by a toxic or immunopotentiating substance. Claim 21 depends from claim 20 and recites that the antibody is modified by a toxic substance (not the toxic substance) selected from a Markush type group. In constructing claim 21 without antecedent reference to the toxic or immunopotentiating substance of claim 20, claim 21 encompasses the combination of an immunopotentiating substance recited in claim 20 together with a toxic substance recited in claim 21. In the same manner, claim 22 embraces the combination as well as the alternative of an immunopotentiating substance. Furthermore, original claim 28 describes an embodiment having a combination of specific embodiments of the features described in claim 60. Original claim 28 depends from original claims 20, 21 and 22. Thus, the general description of features in original claims 20-22 must encompass the specific combination of elements recited in claim 28 and thus also provide support for claim 60.

For at least the foregoing reasons, withdrawal of the rejection of Claim 60 under 35 U.S.C. § 112, first paragraph is respectfully requested.

Claim rejections under 35 USC § 102 and 103:

Claims 44, 57, 58 and 59 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Kolls et al. (PNAS USA, 91:215-219, 1994) The rejection was withdrawn as against claim 40 and its dependant claims, because Kolls et al. does not teach that the antibody is directed against a tumor cell or epitope of an infectious and pathogenic organism. The rejection is respectfully traversed.

Claim 44 has been amended to recite "wherein said at least one protein of interest comprises a heavy chain and a light chain of an antibody . . . directed against a tumor cell or an epitope specific for an infectious and pathogenic organism." Thus, Kolls et al. does not anticipate claim 44 and its dependant claims. Accordingly, withdrawal of the rejection is respectfully requested.

For the sake of a clear record, Applicants also point out that, contrary to the remarks in the present rejection, the TNF receptor fragment immunosuppressor of Kolls et al. cannot be an immunopotentiating substance within the ordinary meaning of potentiating. That which suppresses a biological effect is the antithesis of a potentiating substance. Potentiating is defined as

po·ten·ti·ate *tr.v.* po·ten·ti·at·ed, po·ten·ti·at·ing, po·ten·ti·ates

1. To make potent or powerful.
2. To enhance or increase the effect of (a drug).
3. To promote or strengthen (a biochemical or physiological action or effect).

The American Heritage® Dictionary of the English Language, Fourth Edition
Copyright © 2000 by Houghton Mifflin Company.

Claims 40, 41, 43, 44, 46, 47 and 51-59 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated or under 35 U.S.C. § 103(a) as allegedly obvious over Fell, Jr. et al., U.S. Patent No. 5,314,995 as evidenced by Berkner (Curr. Top. Microbiol. Immunol. 158:39-66). The rejection is respectfully traversed.

Fell does not teach or suggest the all elements recited in claims 40 and 44 and their dependent claims, as amended. Claims 40 and 44 have been amended to recite the elected species, which includes fusion of the antibody at the N-terminus to extracellular domains I and II of CD4. Berkner cannot cure the deficiency in Fell, because Berkner likewise fails to

teach or suggest fusion of an antibody at the N-terminus to extracellular domains I and II of CD4. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 44, and 57-59 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Allaway et al. (WO 94/19091) in view of Berkner (WO/01550). The rejection is respectfully traversed. The Examiner asserts that claims 44 and 57-59 were not distinguished from the references because they do not require an antibody directed against a tumor cell or pathogen. Claim 44 has been amended to recite:

A recombinant adenoviral vector derived from a human adenovirus comprising an exogenous nucleotide sequence encoding all or part of one or more protein or proteins of interest capable of forming a multimer, in a host cell; wherein said at least one protein of interest comprises a heavy chain and a light chain of an antibody modified at the N-terminus by fusion to extracellular domains I and II of CD4 and directed against a tumor cell or an epitope specific for an infectious and pathogenic organism, wherein said heavy and light chains associate in tetramer after synthesis in the host cell, said exogenous nucleotide sequence being placed under the control of the elements necessary for its expression.

Neither Allaway et al. or Berkner , separately or in combination, teach all the elements of Claim 44, as amended, or its dependant claims. As the references fail to teach or suggest all the elements of the claim 44, as amended, the references cannot establish a prima facie case of obviousness. Accordingly, withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

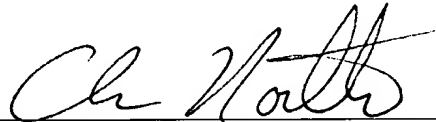
In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: March 8, 2004

By: _____



Christopher L. North, Ph.D.

Registration No. 50,433

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620